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In re: Jen et al.
USSN: 09/464,478
Filed: March 4, 2002
For: METHODS FOR THE DIAGNOSIS AND TREATMENT OF LUNG CANCER
Examiner: Stephen L. Rawlings
Art Unit: 1642

Transmitted herewith:

Transmittal (1 sheet); Fee Transmittal (in duplicate); Response to Restriction Requirement (5 sheets); Petition for Extension of Time (in duplicate)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/646,478
Filing Date	March 4, 2002
First Named Inventor	Jen et al.
Art Unit	1642
Examiner Name	Stephen L. Rawlings
Attorney Docket Number	GA0130C

ENCLOSURES *(check all that apply)*

- ☒ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☒ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) ____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) *(please identify below)*:

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Jennifer D. Tousignant GENZYME CORPORATION
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Date	7/7/04

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Patent
Our Docket: GA0130C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jin Jen et al. Serial No.: 09/646,478 Filed: March 4, 2002 For: METHODS FOR THE DIAGNOSIS AND TREATMENT OF LUNG CANCER	Art Unit: 1642 Examiner: Stephen L. Rawlings

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING FACSIMILE TRANSMITTED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE FACSIMILE NUMBER (703) 872-9306 ON July 7, 2004.

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Request for Reconsideration of Restriction Requirement under 37 C.F.R. §1.143

This communication is being filed in response to a Restriction Requirement mailed April 7, 2004 in connection with the above-identified application. A Response to the Restriction Requirement was originally due on May 7, 2004. As part of this communication, Applicant is filing a Petition for a Two Month Extension of Time, thereby extending the deadline to file a response to July 7, 2004. Accordingly, this Response is timely filed.

Remarks:

Claims 1-30 are pending in the subject application and are subject to a restriction requirement.

Requirement for Restriction under 35 U.S.C. 121 and 372

In the April 7, 2004 Office Action, the Office required restriction under 35 U.S.C. § 121 and 372 to elect a single invention to which the claims must be restricted:

Group I, claim(s) 1, 2, 6, 7, 11, and 30, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed b-myb in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of mRNA transcribed from the proto-oncogene, and a kit for practicing said method.

Group II, claim(s) 1, 3, 6, 8, II, and 30, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed PGP9.5 in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of mRNA transcribed from the proto-oncogene, and a kit for practicing said method.

Group III, claim(s) 1, 4, 6, 9, 11, and 30, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed 8-oxo-dGTPase in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of mRNA transcribed from the proto-oncogene, and a kit for practicing said method.

Group IV, claim(s) 1, 5, 6, 10, 11, and 30, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence

of overexpressed p67 in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of mRNA transcribed from the proto-oncogene, and a kit for practicing said method.

Group V, claim(s) 1, 2, 12, and 13, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed b-myb in a lung cell

sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of the polypeptide or protein encoded by the proto-oncogene.

Group VI, claim(s) 1, 3, 12, and 13, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed PGP9.5 in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of the polypeptide or protein encoded by the proto-oncogene.

Group VII, claim(s) 1, 4, 12, and 13, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed 8-oxo-dGTPase in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of the polypeptide or protein encoded by the proto-oncogene.

Group VIII, claim(s) 1, 5, 12, and 13, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed p67 in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of the polypeptide or protein encoded by the proto-oncogene.

Group IX, claim(s) 14 and 15, drawn to a screen for a potential therapeutic agent for the reversal of a neoplastic condition of the lung characterized by the overexpression of b-myb.

Group X, claim(s) 14 and 16, drawn to a screen for a potential therapeutic agent for the reversal of a neoplastic condition of the lung characterized by the overexpression of PGP9.5.

Group XI, claim(s) 14 and 17, drawn to a screen for a potential therapeutic agent for the reversal of a neoplastic condition of the lung characterized by the overexpression of 8-oxo-dGTPase.

Group XII, claim(s) 14 and 18, drawn to a screen for a potential therapeutic agent for the reversal of a neoplastic condition of the lung characterized by the overexpression of –67.

Group XIII, claim(s) 19, 20, and 24, drawn to a method for reversing a neoplastic condition of the lung characterized by the overexpression of b-myb.

Group XIV, claim(s) 19, 21, and 24, drawn to a method for reversing a neoplastic condition of the lung characterized by the overexpression of PGP9.5.

Group XV, claim(s) 19, 22, and 24, drawn to a method for reversing a neoplastic condition of the lung characterized by the overexpression of 8-oxo-dGTPase.

Group XVI, claim(s) 19, 23, and 24, drawn to a method for reversing a neoplastic condition of the lung characterized by the overexpression of ~67.

Group XVII, claim(s) 25 and 29, drawn to a probe or a primer, or a solid support comprising said probe or primer, wherein said probe or primer comprises SEQ ID NO: 1 or its complement.

Group XVIII, claim(s) 26 and 29, drawn to a probe or a primer, or a solid support comprising said probe or primer, wherein said probe or primer comprises SEQ ID NO: 2 or its complement.

Group XIX, claim(s) 27 and 29, drawn to a probe or a primer, or a solid support comprising said probe or primer, wherein said probe or primer comprises SEQ ID NO: 3 or its complement.

Group XX, claim(s) 28 and 29, drawn to a probe or a primer, or a solid support comprising said probe or primer, wherein said probe or primer comprises SEQ ID NO: 4 or its complement.

Provisional election with traverse in accordance with 37 C.F.R. § 1.143

In compliance with 37 C.F.R. § 1.143, Applicants elect with traverse Group VI, claim(s) 1, 3, 12, and 13, drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of overexpressed PGP9.5 in a lung cell sample, wherein the presence of an overexpressed proto-oncogene is determined by detecting the quantity of the polypeptide or protein encoded by the proto-oncogene.

Request for reconsideration of restriction requirement under 37 C.F.R. § 1.143

Applicants respectfully request a reconsideration and modification of this restriction requirement to the extent that it requires restriction to a single proto-oncogene from the Markush groups in claims 1, 14, and 30. The Office has failed to properly apply restriction practice under PCT Rules 13.1 and 13.2 with respect to the Markush groups present in claims 1, 14, and 30.

PCT Rules 13.1 and 13.2 require a single general inventive concept to find unity of invention of claims. According to PCT Rule 13.2, this requirement can be satisfied where there is a technical relationship involving one or more special technical features. As this relates to Markush-type claims, this requirement is met when the alternatives present in the Markush-type claim are of a similar nature. (MPEP §1850 D)

Claims 1, 14, and 30 contain Markush groups that define alternative genes useful in the practice of the claimed inventions. Applicants have discovered that these genes are proto-oncogenes. These genes are thus similar in nature because 1) they are over-expressed in lung cancer cells and 2) their overexpression is indicative of the neoplastic state of a lung cell. Applicants assert that the similar nature of these Markush group members satisfies PCT Rule 13.2 and that the restriction to a single proto-oncogene is improper.

Since the unity of invention required under PCT 13.2 is satisfied, Applicants respectfully request modification of the restriction requirement to reflect the Office's national restriction practice with respect to Markush-type claims that are directed to independent and distinct inventions in U.S. national applications filed under 35 U.S.C. § 111 outside the PCT. Applicants respectfully suggest that the restriction requirement be modified to require a provisional election of a single, patentably distinct species of proto-oncogene in the claimed methods with respect to which the Markush claim will be fully examined to determine patentability and where the search of the Markush group will be extended to additional members should no prior art be found that anticipates or renders obvious the elected proto-oncogene.

If this requirement is not modified and is made final by the Examiner, Applicants further reserve the right to petition from requirement for restriction under 37 C.F.R. §1.144.

Conclusion:

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

7/7/04
Date

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